Phase II Results Released for Parkinson’s Drug

Top-line results have been reported regarding a Phase II clinical trial of DM-1992, pharmaceutical company Depomed’s investigational novel gastric-retentive, extended-release formulation of carbidopa/levodopa, in patients with advanced Parkinson’s disease with motor fluctuations.

The trial was a randomized, active-controlled, open-label, crossover study evaluating DM-1992 dosed twice daily against a generic version of immediate-release carbidopa/levodopa (IR CD/LD) dosed as needed (mean daily dosing frequency = 4.8). Thirty-four patients with advanced Parkinson’s disease with motor fluctuations enrolled in the study at eight U.S. clinical centers. All enrolled patients completed the study.

Baseline measurements were established over a 3-day patient self-assessment period during which patients were maintained on existing Parkinson’s medications. DM-1992 and IR CD/LD were each administered over a 10-day period that included a 6-day dose optimization period, followed by a 3-day patient self-assessment period and 1 in-clinic day for clinician evaluation and pharmacokinetic measurements.

The primary endpoint for the study is change in percentage “off” time during waking hours, as measured by patient self-assessment during the treatment period relative to the baseline period. Patients’ mean baseline “off” time during waking hours was 5.4 hours per day (32.5%), compared with 4.5 hours (27.2%) during the DM-1992 self-assessment period and 5.5 hours (33.5%) for the IR CD/LD comparator. The reduction in percentage “off” time reported during the DM-1992 patient self-assessment period relative to the IR CD/LD comparator was statistically significant ($p = 0.047$).

Patients who experienced an “off” state for more than 2 hours were permitted to take IR CD/LD as rescue medication. Patients took 1.3 mean daily doses of rescue medication during the DM-1992 patient self-assessment period, compared with 0.2 mean daily doses for the IR CD/LD comparator.

DM-1992 was generally well tolerated in the study. There were no serious adverse events.


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Incontinence App Gives New Meaning to ‘iPad’

A newly released iPhone® and iPad® app—iDry—has been developed to meet the needs of individuals coping with urinary incontinence (UI).

The free app was developed by Jeff Pepper, founder of Three Ten LLC in Oakmont, PA. iDry provides an easy and discreet way to log UI events when they occur, using log data and its built-in database of hundreds of pad and diaper brands to show in detail the progress individuals are making in overcoming UI, including the date when—if trends continue—the user will be completely dry.

iDry also shows exactly how the individual’s UI is affected by various interventions such as exercises, behaviors, diets, drugs, devices, and medical procedures. The free version gives users all the logging, reporting, forecasting, and research tools they need. Upgrading to the premium version unlocks iDry’s advanced features which allows users to:

- Create their own interventions.
- Create their own pad types.
- E-mail charts and log data to physicians.
- Get reminders to do Kegel exercises or anything else users prefer.
- Access advanced charts including “Pad Changes by Hour,” “Progress by Pads Used,” and “Weekly Detail.”

iDry (http://www.idry.org) was developed with the assistance of the National Institute on Aging of the National Institutes of Health and with input from the Department of Urology at a major university and is available through the Apple App Store for use on iPhones, iPads, and the iPod® 4.